DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Visbion Limited
% Mr. Thomas Falcon
Regulatory Manager
Visbion House, Gogmore Lane
Chertsey, Surrey KP16 9AP
UNITED KINGDOM

December 12, 2014

Re: K140797
Trade/Device Name: IPACS Medical Image Management Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 13, 2014
Received: November 17, 2014

Dear Mr. Falcon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140797

Device Name
IPACS (Integrated Picture Archiving and Communications System) Medical Image Management Software.

Indications for Use *(Describe)*
IPACS Medical Image Management Software is used for viewing medical images.

IPACS Medical Image Management Software receives, stores and archives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources). IPACS Medical Image Management Software can be integrated with an institutions existing Hospital Information System (HIS) or Radiology Information System (RIS) for fully integrated electronic patient records.

IPACS Medical Image Management Software can be used to retrieve, process and display medical images and patient information from any connected workstation. Users have access to various image processing and measurement tools to assist them in viewing images. In addition, users can overlay templates on medical images to aid in pre-operative planning and annotations and measurements to aid in diagnosis.

Typical users of IPACS Medical Image Management Software are trained medical professionals, including but not limited to radiologists, technologists and clinicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Revised 510(k) Summary of Safety and Effectiveness

(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. Submitter's name and address:

Visbion Ltd
Visbion House
Gogmore Lane
Chertsey, Surrey
KT16 9AP
United Kingdom

FDA Establishment Registration No. - To be applied for after marketing clearance is given.

2. Submitter's telephone number and fax number:

Tel: 011 44 870 850 3486
Fax: 011 44 870 850 3487

3. Contact person:

Mr. Tom Falcon – Regulatory Manager and FDA Official Correspondent

4. Date this 510(k) summary prepared:

December 12, 2014

5. Trade/proprietary name of the device:

IPACS Medical Image Management Software

6. Classification name and number of the device*:*

FDA Class - II
FDA Classification Name - Picture Archiving and Communications System (PACS)
FDA Regulation Number – 21 CFR 892.2050

7. Legally marketed predicate device to which substantial equivalence is claimed:

eFilm Workstation with Modules:
FDA 510(k) No: K020995 Clearance to market this device was given by FDA on April 12, 2002
FDA Device Classification: Class 2
FDA Regulation Number: 21 CFR 892.2050
FDA Product Code: LLZ

8. Description of the device that is the subject of this premarket notification:

The Visbion IPACS (Integrated Picture Archiving and Communications System) Medical Image Management Software is a vendor-neutral PACS (Picture Archiving and Communication System) solution delivering enterprise-wide diagnostic images and patient reports, available for review at any time, from any location using a standard web browser.

IPACS is a single healthcare platform that allows the seamless acquisition of images from multiple types of imaging devices from a range of different equipment suppliers. It

is a true clinical repository with the ability to harmonise all departments within a hospital. The approach to connectivity is based on three key standards; Digital Imaging and Communications in Medicine (DICOM) 3.0, Health Level Seven International (HL7) and Integrating the Healthcare Enterprise (IHE).

Using a standard web browser registered users have the ability to log in thus provide secure access to images from diagnostic workstation in hospitals and consulting rooms plus from off-site storage facilities, 24 hours a day.

The device is constructed from the four software elements. These elements are combined according to the configuration required by the user. These terms are used by the user, IPACs being a general term to consolidate the following four elements:

Image Archive
Image Viewer
Image Web
Image Importer

9. Intended use and indication for use:

IPACS Medical Image Management Software is used for viewing medical images.

IPACS Medical Image Management Software receives, stores and archives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources). IPACS Medical Image Management Software can be integrated with an institutions existing Hospital Information System (HIS) or Radiology Information System (RIS) for fully integrated electronic patient records.

IPACS Medical Image Management Software can be used to retrieve, process and display medical images and patient information from any connected workstation. Users have access to various image processing and measurement tools to assist them in viewing images. In addition, users can overlay templates on medical images to aid in pre-operative planning and annotations and measurements to aid in diagnosis.

Typical users of IPACS Medical Image Management Software are trained medical professionals, including but not limited to radiologists, technologists and clinicians.

10. Technological characteristics:

IPACS is a stand-alone software package comprising four components that can be installed on a number of different hardware platforms, providing that the minimum hardware specification requirements are met. The system can transmit images to remote viewing workstations over a medical imaging network. None of the software components makes contact with the patient, nor do they control any life-sustaining devices. A qualified physician will review and interpret the images and information displayed in order to make clinical decisions.

The following comparison of the technological characteristics of the IPACS Medical Image Management Software and the predicate device, eFilm Workstation with Modules, illustrates that the characteristics are the same.

Comparison of Technological Characteristics:

Ref. No.	Technological Characteristic	Candidate Device IPACS Medical Image Management Software	Predicate Device eFilm Workstation with Modules
1	Type of Device	Software only product residing on a PC Workstation or server.	Software only product residing on a PC Workstation or server.
2	Type and Source of Images	Digital images received from various modalities and digitised images via a network or the internet.	Digital images received from various modalities and digitised images via a network or the internet.
3	Scope of Image Processing	Displays files received as images from any third party modality where the third party manufacturer has provided appropriate DICOM drivers	Displays files received as images from any third party modality where the third party manufacturer has provided appropriate DICOM drivers
4	Display of an Image	On a visual display unit. A hardcopy can be sent to a suitable third party laser printer.	On a visual display unit. A hardcopy can be sent to a suitable third party laser printer.
5	Processing of an Image	Permits interactive positioning of an image.	Permits interactive positioning of an image.
		Permits interactive sizing of an image (length, angle, area etc).	Permits interactive sizing of an image (length, angle, area etc).
		Permits interactive rotation of an image.	Permits interactive rotation of an image.
		Permits interactive adjustment of contrast and brightness of an image.	Permits interactive adjustment of contrast and brightness of an image.
		Not applicable.	Permits mechanical linking of components associated with prosthetic templates and trauma templates (fixation device) – via third party accessories - see below.
		Not applicable.	Permits integration of third party accessories such as orthopaedic templating and trauma processing.
		Permits interactive display or three dimensional images.	Permits interactive display or three dimensional images.
		Permits interactive rendering on an image.	Permits interactive rendering on an image.
		Supports Hanging Protocols.	Supports Hanging Protocols.

Ref. No.	Feature	Candidate Device IPACS Medical Image Management Software	Predicate Device eFilm Workstation with Modules
6	Means of Collecting Data	From pre-obtained digital images.	From pre-obtained digital images.
7	Processing of Data	The software processes data and provides an indication of the extent of quality loss. Images are stored lossless.	The software processes data and provides an indication of the extent of quality loss. Images are stored lossless.
8	Standards Compliance	Digital Imaging and Communications in Medicine (DICOM) 3.0 Joint Photographic Experts Group (JPEG) Standard Health Level Seven International (HL7) Integrating the Healthcare Enterprise (IHE)	Digital Imaging and Communications in Medicine (DICOM) 3.0 Joint Photographic Experts Group (JPEG) Standard Health Level Seven International (HL7) Integrating the Healthcare Enterprise (IHE)
9	Stand–alone Software	Yes	Yes
10	Can be used on Multiple Hardware Platforms	Yes - provided that stated minimum hardware requirements are met.	Yes - provided that stated minimum hardware requirements are met.
11	Transmit Images to Remote Viewing Stations Over an Imaging Network	Yes	Yes

From the above information it is concluded that the IPACS Medical Image Management Software is substantially equivalent to the eFilm Workstation with Modules predicate device.

This concludes the 510(k) Summary.